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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,469	11/03/2001	David W. Buck	17810-510 NATL	3254
7590	05/19/2005		EXAMINER	
Ivor R Elrifi Mintz Levin Cohn Ferris Glovsky & Popeo One Financial Center Boston, MA 02111			HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,469	BUCK ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 52-65 and 67-75 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 52-65, 67 and 71-75 is/are allowed.
- 6) Claim(s) 68-70 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2/28/05</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/05 has been entered.

2. The rejection of claims 66-67 & 71-72 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to either the cancellation or amendment of the claims.

3. The rejection of claims 61-62, under 35 U.S.C. 112, second paragraph, for lack of proper antecedent basis is withdrawn due to the amendment of the claims.

4. The rejection of claim 72 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

5. The rejections of claims 73-75 under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn due to the amendment of the claims.

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6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Applicants' arguments filed 2/28/05 have been fully considered but they are not deemed to be persuasive.

8. Claims 52-65, 67 & 71-75 are allowed.

9. Claims 68-70 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a population of highly enriched human CNS stem cells using publicly available and identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating highly enriched populations of human CNS stem cells from adult brain or spinal cord areas or from undefined generic neural cell cultures where no neural stem cells exist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record for cancelled claims 1-20, 22, 24-26 in Paper NOS: 20040405 & 20041129, and as follows.

Applicants argue on pages 8-11 of the response that "the claimed neurosphere/ neural stem cell compositions can be obtained from many regions in the brain, not merely the subependymal regions or the dentate gyrus", cites various passages within Weiss out of context, and cites Engel Industries Inc. v. Lockformer Company, John Hopkins University v. CellPro, Inc., and In re Marzocchi. In contrast to Applicants' assertions, the proper context is found in

column 2 of Weiss where they state that “[u]nlike many other cells found in different tissues, the differentiated cells of the adult mammalian CNS have little or no ability to enter the mitotic cycle and generate new nerve cells” (lines 27-29). “Neurogenesis, the generation of new neurons, is complete early in the postnatal period” (lines 35-36), and that “the generation of new CNS cells in adult primates does not occur” (lines 44-45). Not until later was it discovered that in limited and specific regions of the adult brain, multipotent stem cells can exist, in which column 13 (lines 51-55) then states that “[n]eural stem cells have [now] been isolated from a variety of *adult CNS ventricular regions* [emphasis added], including...”. Thus, there is “reason to doubt the objective truth” of Applicants’ statements, because Applicants’ assertions and claims are not commensurate in scope with that accepted within the art at the time of filing Applicants’ invention, as illustrated by a thorough reading of Weiss et al.

In arguendo, Arsenijevic et al. (2001) alternatively teach that even 2 years after the claimed priority date that it was “unexpected... [to find] multipotent cells in the cortex and the amygdale” (pg. 58, 2nd column), and that their “study is the first evidence that primitive precursors such as multipotent precursors exist in the adult human cortex and can reside far from the ventricles” (pg. 48, Abstract). Accordingly the court in *In re Hogan and Banks*, 194 USPQ 527 (1977) makes clear that “enablement must be established in the specification *at the time of filing* and is to be *commensurate in scope* with the stated claims [emphasis added]”. Therefore, in contrast to Applicants’ assertions, the state of the art is consistent with the current rejection that only certain specific areas of the adult brain contain multipotent neural stem cells (i.e., including hippocampus/dentate gyrus) at the time of filing Applicants’ invention. Thus, as previously made of record, an invitation for others to discover other “neural or neural-derived”

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regions that do not reasonably contain neural stem cells, as encompassed by these claims, does not reasonably enable the current claims at the time of filing Applicants' invention, as illustrated by the teachings of Weiss patent and Arsenijevic et al. (2001); thereby, requiring undue experimentation for one of skill within the art to know how to make the instant claimed method work; further consistent with that held by the court in *Novo Nordisk v. Genentech* previously made of record.

Thus, Applicants' arguments remain unpersuasive for the reasons made of record.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
May 9, 2005

**ROBERT C. HAYES, PH.D.
PATENT EXAMINER**